GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2020
ANSWERED ON:21.07.2004
CLEARANCE OF NEW DRUGS
Chowdhury Shri Adhir Ranjan

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the details of the new drugs cleared for marketing in the country since 2002;

(b) the details of the products and companies which have submitted post marketing surveillance reports to Drug Controller General of India;

(c) the names of the companies which have defaulted and not submitted post market surveillance; and

(d) the reaction of the Government thereto?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a)to(d): The details of New Drugs cleared for marketing in the country since 2002 is enclosed at Annexure-1. These details are also made available on Directorate General of Health Service's website www.cdsco.nic.in. Consequent to approval, the firms are advised to undertake Post Marketing Surveillance and reports are being submitted to the Office of the DCG(I).

The Post Marketing Surveillance (PMS) are to be undertaken by the Pharmaceutical firm for a period of two years from its approval. However, time for submission of PMS study report depends upon the time by which the product is actually marketed in the country.

For the products approved from January, 2002, the PMS study reports, after completion of two years have been furnished by most of the firms.